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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/731,528

12/09/2003

Laszlo Prokai

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EXAMINER

BADIO, BARBARA P

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 06/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/731,528	<b>Applicant(s)</b> PROKAI ET AL.	
	<b>Examiner</b> Barbara P. Badio, Ph.D.	<b>Art Unit</b> 1617	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-25 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-12 and 16-25 is/are rejected.
- 7) ☒ Claim(s) 6 and 13-15 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/04;3/05;10/05</u> . | 6) <input type="checkbox"/> Other: ____.  |

**First Office Action on the Merits**

***Double Patenting***

1. Claims 2-5 and 20 are objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Note: The recitation of the enzymatic catalysis of the compounds utilizing various agents or the lack of systemic side effect are not limiting because the present specification does not make any differentiation between the claimed compounds. For example, the present specification does not indicate quinols that would be reduced with NADH versus those that would be reduced with NADPH.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-5, 8, 9, 17-20 and 23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the quinols set forth in the present specification, does not reasonably provide enablement for all quinols. The specification

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does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are (1) the nature of the invention, (2) the breadth of the claims, (3) the state of the prior art, (4) the predictability or unpredictability of the art, (5) the amount of guidance or direction presented, (6) the presence or absence of working examples, (7) the relative skill in the art and (8) the quantity of experimentation necessary. When the above factors are taken into consideration, the examiner's position is that one skilled in the art could not perform the invention commensurate in scope with the instant claim without undue experimentation.

The instant claims encompass the utilization of every "steroidal quinol" known or unknown that might be converted to a biologically active phenolic A-ring steroid compound *in vivo*. However, the present specification lacks guidance/direction that would enable the skilled artisan in the art to determine other steroid quinols, apart from those set forth, that would be converted to a biologically active phenolic A-ring steroid as presently claimed. Therefore, in order to practice the claimed invention commensurate in scope with the instant claims the skilled artisan in the art would first have to test every steroidal quinols in order to obtain those that would be converted *in vivo* as recited by the instant claims. Because of the lack of guidance or direction in the

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present specification, the experimentation necessary to make said determination would be undue.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-5, 7-9, 16-20 and 23-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are indefinite for the following reasons:

(a) claim 1 recites "a steroidal quinol that is converted to a biological active phenolic A ring steroid compound" but lacks structural characteristics of said compounds. The skilled artisan in the art would be unable to readily envision the claimed compounds and, thus, the claim is indefinite.

(b) claims 2-5 recite the reduction of the claimed quinol in the presence of various reducing agents and claim 20 recites "wherein the steroidal quinol does not confer systemic side effects". However, the present specification lacks differentiation between the claimed quinols and, thus, the metes and bound of the instant claims are indefinite.

(c) claims 7 and 16 recite steroidal quinols derived from specific estrogen but lack identification of said quinols and, thus, the claimed invention is unclear.

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***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Lunn et al. (Tetrahedron, 1968).

Lunn et al. teaches the production and crystallization of 2-(1-adamantyl)-3-hydroxyestra-1,3,5(10)-trien-17-one (see page 6774, compound #2). The compound and composition taught by the reference are encompassed by the instant claims.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-5, 8-12, 17, 20 and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chamberlain et al. (US 6,258,856) in view of Jin et al. (US 2,910,486).

Chamberlain et al. teaches the treatment of cataract or cataract-like disorders in mammals utilizing estrogenic compounds (see the entire article, especially col. 3, line 2 – col. 4, line 64). The reference also teaches various means of administration including the utilization of membranous ocular patch (see for example, Abstract).

The instant claims differ from the reference by reciting quinols. However, Jin et al. teaches 10-hydroxyestra-1,4-diene-3,17-diones and their estrogenic property (see the entire article, especially col. 1, lines 29-31). Therefore, it would have been obvious to the skilled artisan in the art at the time of the present invention to utilize the compounds of Jin et al. in the treatment of cataract or cataract-like disorder as taught by Chamberlain et al. The motivation is based on the teaching of Chamberlain et al. that estrogens are useful in the treatment of cataract or cataract-like disorders and the teaching by Jin that 10-hydroxyestra-1,4-diene-3,17-diones are estrogenic.

#### ***Allowable Subject Matter***

10. Claims 6 and 13-15 are objected to as being dependent upon a rejected base claim.

#### ***Other Matters***

11. It is requested that applicant update the cross-reference by inserting the patent no. of the parent application.


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***Telephone Inquiry***

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Barbara P. Badio, Ph.D.  
Primary Examiner  
Art Unit 1617

BB

June 22, 2006